

K051793

AUG 17 2005

Page 1 of 2

[1] 510(k) SUMMARY

[2] Ansell Healthcare Products LLC  
1635 Industrial Road  
Dothan, AL 36303

Contact: Lon D. McIlvain, Vice President Regulatory Affairs  
Telephone: (334) 615-2562  
Fax: (334) 615-2568

June 29, 2005

[3] Trade Name: Encore Sterile Powder-Free Polymer Coated Latex  
Surgical Glove With Hydrasoft Coating (containing Glycerine)  
And Protein Labeling Claim (50 micrograms or less)

Common Name: Surgical Gloves

Classification Name: Surgeon's Glove

[4] Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove With Hydrasoft  
Coating (containing Glycerine) And Protein Labeling Claim (50 micrograms or less)  
meet all of the requirements of ASTM D 3577, Type 2.

[5] Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove With Hydrasoft  
Coating (containing Glycerine) And Protein Labeling Claim (50 micrograms or less)  
meet all of the current specifications of ASTM D 3577, Type 2.

[6] Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove With Hydrasoft  
Coating (containing Glycerine) And Protein Labeling Claim (50 micrograms or less)  
are sterile disposable devices intended to be worn by operating room personnel to  
protect a surgical wound from contamination. These latex gloves contain 50  
micrograms or less of water extractable protein per gram.

[7] Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove With Hydrasoft  
Coating (containing Glycerine) And Protein Labeling Claim (50 micrograms or less)  
are summarized with the following technological characteristics  
compared to ASTM or equivalent standards.

<u>Characteristics</u>	<u>Standard</u>
Dimensions	Meets ASTM D 3577
Physical Properties	Meets ASTM D 3577, Type 2
Freedom from Holes	Meets ASTM D 3577 Meets ASTM D 5151
Powder-Free	Meets ASTM D 6124 Powder content $\leq$ 2 mg per glove

Biocompatibility:

FHSA Skin Irritation Study  
ISO Maximization Sensitization Study  
Cytotoxicity Study using  
the End-Point Titration Method

Passes  
Passes

Non-Toxic at 24 hours

Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove With Hydrasoft Coating (containing Glycerine) And Protein Labeling Claim (50 micrograms or less) have the additional characteristic:

Protein Label Claim: This latex glove contains 50 micrograms or less of total water extractable protein per gram

Meets ASTM D 5712-99  
Standard Test Method for  
Analysis of Protein in  
Natural Rubber and Its  
Products

- [8] The performance test data of the non-clinical tests are the same as mentioned immediately above.
- [9] Clinical data is not needed for medical gloves or for most devices cleared by the 510(k) process.
- [10] It is concluded that Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove With Hydrasoft Coating (containing Glycerine) And Protein Labeling Claim (50 micrograms or less) are as safe, as effective, and perform as well as the glove performance standards referenced in Section 7 above and therefore meet:
  - ASTM listed standards,
  - FDA hole requirements, and
  - labeling claims for the product.
- [11] This summary will include any other information reasonably deemed necessary by the FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 17 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ansell Healthcare Products, LLC  
C/O Ms. Cynthia A. Ingram  
Regulatory Affairs Manager, Americas  
1635 Industrial Road  
Dothan, Alabama 36303

Re: K051793

Trade/Device Name: Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove  
with Hydrasoft coating (containing Glycerine) and Protein  
Labeling Claim (50 micrograms or less)

Regulation Number: 21 CFR 878.4460

Regulation Name: Surgeon's glove

Regulatory Class: I

Product Code: KGO

Dated: June 30, 2005

Received: July 1, 2005

Dear Ms. Ingram:

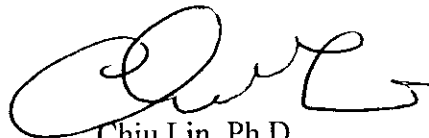
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

3.0 Indications for Use Statement:

INDICATIONS FOR USE

510(K) Number (if known): K051793

Device Name: Encore Sterile Powder-Free Polymer Coated Latex Surgical Glove with Hydrasoft coating (containing Glycerine) and Protein Labeling Claim (50 micrograms or less)

Indications For Use:

These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination. These latex gloves contain 50 micrograms or less of water extractable protein per gram.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH Office of Device Evaluation (ODE)

Shirley A. Murphy MD 8/16/05  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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